



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 17 1998

Food and Drug Administration  
Washington, DC 20204

*Rec'd 3/26/98 jib*

John P. Troup  
Vice President Scientific Affairs  
General Nutrition Corporation  
300 Sixth Avenue  
Pittsburgh, Pennsylvania 15222

Dear Mr. Troup:

This is in response to your letter of February 13, 1998 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that General Nutrition Corporation. is making the following statement, among others, for the products "GNC Chelated Zinc," "NNW Chelated Zinc," "NNW Zinc Complex Lozenge," and "NNW Zinc Picolinate w/copper:"

"...important for wound healing and cellular repair"

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate disease, in that they are intended to treat, mitigate, or cure wounds. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 USC 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Philadelphia District Office, Compliance Branch, HFR-MA140

975-0163

LET 152

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (file)

HFS-450 (r/f, file, OSN#57210)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

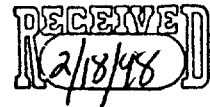
GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:3/4/98

init:GCF-1:DDorsey:3/6/98

f/t:rjm:HFS-456:3/11/98:57210.adv:disc26

February 13, 1998



Ms. Linda S. Kahl, Ph.D.  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W. (HFS-450)  
Washington, DC 20204

Dear Dr. Kahl:

Pursuant to section 403(r)(6) of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), General Nutrition Corporation, located at 300 Sixth Avenue, Pittsburgh, Pennsylvania 15222 ("GNC"), hereby notifies the Food and Drug Administration that it is marketing dietary supplements that bear a nutritional support statement on their labels. Enclosed please find a listing of the products and their statements of nutritional support.

As required, the product labels contain the disclaimer that this statement has not been evaluated by the Food and Drug Administration and that the product is not intended to diagnose, treat, cure, or prevent any disease. Two (2) copies of this notification are enclosed for your convenience.

On behalf of GNC, I hereby certify that the information contained in this notice is complete and accurate and that GNC has substantiation that the statements are truthful and not misleading.

Very truly yours,

A handwritten signature in dark ink, appearing to read "John P. Troup". The signature is written in a cursive, somewhat stylized font.

John P. Troup  
Vice President  
Scientific Affairs

JPT:mo  
Enclosures

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VITAMIN K		
GNC Mega Men	1/29/98	Vitamin K which is necessary for blood clotting.

YERBA MATE		
Optibolic Optimax	1/29/98	Yerba Mate and Green Tea provide caffeine, which have invigorating qualities.

ZINC		
GNC Chelated Zinc	1/29/98	Zinc is important for wound healing and cellular repair. Zinc is also required for proper growth and normal reproductive function.
GNC Ultra Zinc Lozenge	1/29/98	Zinc and Echinacea help support natural resistance.
NNW Calcium & Magnesium w/ Zinc	1/29/98	Zinc is important for cellular repair.
NNW Chelated Zinc	1/29/98	Zinc is important for wound healing and cellular repair.
NNW Zinc Complex Lozenge	1/29/98	"
NNW Zinc Picolinate w/ Copper	1/29/98	"